Taking a closer look.

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To whom it may concern

New EFSA publication on the toxicological evaluation of fosetyl

Here: Approval of the laboratories of the quality circle relana®

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Introduction

As of 24 May 2018, the EFSA Journal 2018; 16 (7): 5307 published a so-called "peer review" on the pesticide risk assessment of the active substance fosetyl:
"*Peer review of the pesticide risk assessment of the active substance fosetyl*"

In this context, there has been some confusion among the stakeholders (producers, distributors, food retailers, laboratories, etc.) on how to classify and apply the "new" toxicological parameters listed in this publication. In particular, the first-time "obvious" mention of an ARfD value for the substance "phosphonic acid" (inter alia main degradation product of fosetyl) has led to confusion.

After detailed study of the above cited publication, including the appendix ("Appendix A", same source as above), as well as other relevant documents in this context, the situation is, in our view, as follows:

1.) The publication refers to the toxicological risk assessment of fosetyl, not of phosphonic acid. This becomes clear already by the title.
The reason for the re-evaluation is the request of companies from the plant protection industry for renewal of the approval of the active substance fosetyl in accordance with Article 14 of Regulation (EC) No 1107/2009.

2.) The conclusions of the publication have been derived from studies on the use of fosetyl as a fungicide in grape, citrus and pome fruit as submitted by the complainants.

3.) The derivations and conclusions regarding phosphonic acid are therefore not based on studies and information that include the active substance phosphonic acid. All derivatives of phosphonic acid are indirect in nature and not studied or evaluated on phosphonic acid itself:

On page 10 of the publication: "*Since phosphonic acid is the major metabolite in rat (73% in the urine) its toxicity (...) is covered by the studies performed with fosetyl-Al.*"

4.) It is noted that additional information needs to be requested from the applicants, as there are still areas with information gaps.

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5.) An information gap relates to the active substance (fosetyl) and its relevant metabolites in terms of side effects on human health.

6.) Data and information gaps have also been identified for reliable DT50 and DT90 values from submitted trials and monitoring data.

7.) Further information gaps exist in the submitted validation data for residue analytical methods as well as in independent laboratory validations of residue tests in water and soil.

8.) A risk has been identified for acute uptake of fosetyl in relation to the maximum levels currently set for grape, apple and pearaceous products in accordance with Regulation (EC) No 396/2005. It is therefore noted that these maximum levels should be adjusted.

9.) A new residue definition is proposed in this context (s. Appendix A, page 8):
Fosetyl-Al = "*Sum of fosetyl and phosphonic acid and their salts, expressed as phosphorous acid*".
In this respect, all previous MRLs must be recalculated and adjusted.

10.) Suggestions on the toxicological parameters (reference values) ADI, ARfD, AOE and AAOEL are given on page 16 in Appendix A "List of endpoints for the active substance and the representative formulation"
made by Fosetyl-Al:
"*Summary[3] (Regulation (EU) No 1107/2009, Annex II, point 3.1 and 3.6)*" with footnote 3: "*If available include, therefore, reference values for metabolites*".

Since there is currently no known ARfD value for phosphonic acid (see eg Disodium phosphonate SANCO / 10416/2013 rev. 0 16 July 2013/23 March 2018, page 4: "ARfD: Not relevant"), there is thus no value for phosphonic acid included.

The proposed value for the acute reference dose (ARfD) for Fosteyl-Al is 1 mg / kg bw per day.

11.) This is repeated on page 34 of the Appendix, in the context of ARfD value exhaustion calculations using the EFSA PRIMo model:
"*Residue definition for risk assessment: sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid.*"; "*ARfD: 1 mg / kg bw*".

A passage in the EFSA publication "Peer review of the pesticide risk assessment of the active substance fosetyl" (page 13, 2nd paragraph, penultimate sentence) is in our view incorrect and has led to great uncertainty. Considering the 11 points listed above, the wording is:
"*In contrast and considering the **ARfD of 1mg / kg bw set for phosphonic acid**, in excess of the ARfD was identified for numerous commodities.*"
incomprehensible and in our opinion not applicable.

As noted above, in Appendix A to the EFSA publication and also in the document itself (see page 10, 3rd paragraph: "*The acute reference dose (ARfD) and the acute AOEL (AAOEL) for Fosetyl-Al are 1 mg / kg bw per day based on ...* "), the toxicological reference values refer exclusively to **fosetyl-Al**.

Summary
The document "Peer review of the pesticide risk assessment of the active substance fosetyl" and the accompanying Appendix A, both published in the EFSA Journal 2018; 16 (7): 5307, are from our current point of view, not suitable for justifying a new, conclusive toxicological evaluation of the substances fosetyl-Al, fosetyl and phosphonic acid.
In no case can a unique ARfD value for the substance phosphonic acid be deduced from this document. The proposal for a new ARfD value mentioned in the document refers to: "**Sum of fosetyl, phosphonic acid and its salts, expressed as phosphonic acid"**.

The publication refers to the provision of the applicant's data (pesticide industry asking for a re-approval of Fosetyl-Al) and documents on the active substance fosetyl. Conclusions regarding the main metabolite *phosphonic acid* are not based on submitted data on phosphonic acid, but assume, that the data for fosetyl are also applicable to phosphonic acid ("*The reference values of the parent are applied to phosphonic acid*"; Appendix A page 15). This seems doubtful and not substantiated since the risk assessments of disodium phosphonate (see Disodium phosphonate SANCO / 10416/2013 rev.0) and potassium phosphonate (see Potassium phosphonate SANCO / 10416 / 2013 rev.2) conclude, that the determination of an ARfD value is not necessary ("*not relevant*"). These assessments were prepared on the basis of submitted data of the applicants for phosphonates (salts of phosphonic acid).

As it stands as present, and considering the large amount of information- and data-gaps, the conclusions regarding the application of the new toxicological reference values proposed in this document and regarding the proposed amended residue definition, are not yet substantive enough to recommend the immediate application of these reference levels.

It should be highlighted that the proposal for the new acute reference dose is NOT related to the substance *phosphonic acid*, but to fosetyl-Al, taking into consideration the proposed definition: "Total of fosetyl and phosphonic acid and their salts, expressed as phosphonic acid".
The wording in the EFSA document on page 13 for an ARfD value for phosphonic acid "... *considering the ARfD of 1 mg / kg bw set for phosphonic acid* ..." is in our opinion neither proven nor comprehensible and should therefore not be used.

Finally, it is to conclude that this publication causes confusion at several stakeholder levels, as the outcome is not in line with other EFSA statements (f.ex. related to Disodium phosphonate) and has some major deficiencies in the consequences of how to apply the proposed endpoints in practice.

With kind regards

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